

Remarks

Claims 41-80 are pending in the subject application. Applicant gratefully acknowledges the Examiner's indication that claim 70 is free of the prior art and allowed, and that all prior rejections have been withdrawn. By this Amendment, Applicant has amended claims 63, 72, and 73 and added new claims 81-85. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 41-85 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicant gratefully acknowledges the Examiner's acknowledgment of Applicant's claim of priority under 35 USC §119(e). However, Applicant would also like to bring to the Examiner's attention Applicant's claim in the subject application under 35 USC §120 to the benefit of the filing date of U.S. Application No. 08/919,421 (hereinafter the '421 application, which was filed August 27, 1997), which claims the benefit of U.S. provisional Application No. 60/025,800, filed August 27, 1996. Applicant refers the Examiner to the "Cross-Reference to Related Applications" section at page 1, lines 6-9, of the subject specification. This benefit claim to the '421 application was present in the subject application as filed and has not been canceled by any previous amendments. Although the executed Declaration/Power of Attorney form submitted in the subject application does not list the '421 application in a benefit claim under 35 USC §120, the Patent Office rules do not require that such a benefit claim be made on a Declaration/Power of Attorney (see 37 CFR 1.63). Applicant also notes that the Examiner acknowledged Applicant's claim of benefit to the '421 application under 35 USC §120 in the Office Action dated September 13, 2002. If the Patent Office file indicates that the subject application does not contain the "Cross-Reference to Related Applications" section as described above, Applicant respectfully requests that the Examiner contact Applicant's undersigned representative.

Claim 63 is objected to on the grounds that the term "menometrorrahgia" is misspelled. Applicant gratefully acknowledges the Examiner's careful review of the claims. In accordance with the Examiner's suggestion, Applicant has replaced the word "menometrorrahgia" with "menometrorrahagia" in claim 63. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claims 72 and 73 are rejected under 35 USC §101 as being directed to non-statutory subject matter on the grounds that the claims read on a natural process. Applicant respectfully asserts that the claims are not directed to non-statutory subject matter. However, by this Amendment, Applicant has amended the claims to recite that an effective amount of a composition that decreases (claim 72) or increases (claim 73) levels of *ebaf* nucleic acid or *ebaf* protein, or that decreases or increases production or biological activity of *ebaf* protein, is administered to the female animal. Thus, the claims recite a positive step of administering an effective amount of a composition to a female animal. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §101 is respectfully requested.

Claims 72 and 73 are rejected under 35 USC §112, first paragraph, as nonenabled by the subject specification. The Examiner asserts that the specification does not enable the claims because the intended use is accomplished in the claims without administration of any product or composition. Applicant respectfully asserts that the claims are enabled by the subject specification. However, as indicated in response to the rejection under 35 USC §101, Applicant has amended the claims to recite that a composition is administered to the female animal that decreases or increases levels of *ebaf* nucleic acid or *ebaf* protein, or that decreases or increases production or biological activity of *ebaf* protein. The composition can comprise, for example, an *ebaf* protein, an antibody that binds to an *ebaf* protein and blocks activity, or a nucleic acid that is antisense to *ebaf*. New dependent claims 81-85 recite specific elements of a composition that can be used in the claimed invention. Support for these new claims can be found throughout the specification including, for example, at page 8, lines 24-26; page 19, lines 23-27; and page 20, lines 12-19. Reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claims 72 and 73 are rejected under 35 USC §112, second paragraph, as indefinite on the grounds that means for decreasing or increasing the expression of an *ebaf* nucleic acid or an *ebaf* protein have not been provided or administered. Applicant respectfully asserts that the claims as filed are definite. However, in order to lend greater clarity to the claimed invention, Applicant has amended the claims to recite that a composition that decreases or increases levels of *ebaf* nucleic acid, or *ebaf* protein, or the production or biological activity of *ebaf* protein, is administered to the

female animal. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claims 41-69 and 71 are rejected under 35 USC §102(e) as anticipated by Tabibzadeh *et al.* (U.S. Patent No. 5,916,751, which issued from the '421 application) in light of Kothapalli *et al.* (1997) which was incorporated by reference in the Tabibzadeh *et al.* patent. In addition, claims 74-80 are rejected under 35 USC §103(a) as obvious over Tabibzadeh *et al.* (U.S. Patent No. 5,916,751) (Applicant assumes that the Examiner is relying on the 35 USC §102(e) date of the Tabibzadeh *et al.* patent for purposes of the §103 rejection because the Tabibzadeh *et al.* patent issued June 29, 1999, which is after the April 29, 1999 filing date of the subject application.). The Examiner asserts that the Tabibzadeh *et al.* patent discloses detecting or diagnosing endometrial irregularity in a female, including the screening of endometrial tissue or blood for abnormal levels of *ebaf* nucleic acid or proteins. The Examiner relies on the incorporated Kothapalli *et al.* reference as teaching that *ebaf* expression is associated with endometrial bleeding. The Examiner also states that the Tabibzadeh *et al.* patent discloses the utilization of nucleic acid detection and protein detection kits for the determination of *ebaf* nucleic acid expression and/or *ebaf* protein/peptide biological activity in a biological sample. In regard to the obviousness rejection, the Examiner concludes that it would have been obvious to the ordinarily skilled artisan to formulate the necessary reagents for the determination, detection or diagnosis of an *ebaf*-related condition in view of the teachings of the Tabibzadeh *et al.* patent. Applicant respectfully traverses the rejections under 35 USC §102(e) and 35 USC §103(a).

As noted above, the subject application claims the benefit of the effective filing date of the '421 application (*i.e.*, August 27, 1996). The Tabibzadeh *et al.* patent issued from the '421 application. Applicant further notes that the Kothapalli *et al.* reference was apparently published sometime in or around May 1997 which is after the August 27, 1996 filing date of the 60/025,800 provisional application. In view of Applicant's claim to the benefit of the August 27, 1996 filing date of the '421 application, Applicant respectfully asserts that the Tabibzadeh *et al.* patent that issued from the '421 application is not effective prior art against the subject application under 35 USC §102(e). Accordingly, reconsideration and withdrawal of the rejections under 35 USC §§102(e) and 103(a) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant's agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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